



6-20-05

IFW

PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|  |   |                        |                    |
|--|---|------------------------|--------------------|
| <b>TRANSMITTAL FORM</b><br><i>(to be used for all correspondence after initial filing)</i> |   | Application Number     | 10/760,100         |
|  |   | Filing Date            | January 16, 2004   |
|  |   | First-Named Inventor   | Jonathan C. Heller |
|  |   | Art Unit               | 1631               |
|  |   | Examiner Name          | Eric S. Dejong     |
| Total Number of Pages in This Submission   | 6 | Attorney Docket Number | 29191-707.501      |

| ENCLOSURES (Check all that apply)   |  |   |
|---|--|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Response to Missing Parts<br>under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) | <input type="checkbox"/> After Allowance communication to<br>Technology Center (TC)<br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC<br>(Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input type="checkbox"/> Other Enclosure(s)<br>(please identify below): return<br>receipt postcard |
| <b>Remarks</b>  |  |   |

| SIGNATURE OF APPLICANT, ATTORNEY OR AGENT |  |
|---|--|
| Firm or Individual name                   | U. P. Peter Eng, Reg. No. 39,666, WILSON SONSINI GOODRICH & ROSATI |
| Signature                                 |  |
| Date                                      | June 17, 2005  |

| CERTIFICATE OF TRANSMISSION/MAILING   |                |      |               |
|---|----------------|------|---------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. |                |      |               |
| Typed or printed name   | Queenie B. Ngo |      |               |
| Signature   |                | Date | June 17, 2005 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



EXPRESS MAIL LABEL NO.: EV 518898446 US

PATENT

Attorney Docket No. 29191-707.501

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|   |   |                           |
|---|---|---------------------------|
| In re Application                       | ) | <u>PATENT APPLICATION</u> |
|   | ) |                           |
| Inventor(s): Jonathan C. Heller, et al. | ) |                           |
|   | ) | Art Unit: 1631            |
| Application No.: 10/760,100             | ) |                           |
|   | ) | Examiner: Eric S. Dejong  |
| Filed: January 16, 2004                 | ) |                           |
|   | ) |                           |
| Title <b>ASSAY CUSTOMIZATION</b>        | ) |                           |
|   | ) |                           |

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- ☒ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
  - ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
  - ☒ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
  - ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☐ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; or
  - ☐ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
  - B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No. ), copies are not enclosed herewith.
    - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
  - ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)

- ☒ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.29191-707.501).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: \_\_\_\_\_

6/17/05

By: \_\_\_\_\_

U.P. Peter Eng (Reg. No. 39,666)

650 Page Mill Road  
Palo Alto, CA 94304-1050  
(650) 493-9300  
Customer No. 021971



Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

|  |   |    |   |                          |                    |
|--|---|----|---|--------------------------|--------------------|
| <b>Substitute for form 1449/PTO</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |                    |
|  |   |    |   | Application Number       | 10/760,100         |
|  |   |    |   | Filing Date              | January 16, 2004   |
|  |   |    |   | First Named Inventor     | Jonathan C. Heller |
|  |   |    |   | Art Unit                 | 1631               |
|  |   |    |   | Examiner Name            | Eric S. Dejong     |
| Sheet  | 1 | of | 2 | Attorney Docket Number   | 29191-707.501      |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
|                       |                          | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       |                          | US-2003/0153007                          | 08-14-2003                     | Chen, et al.                                       |   |
|                       |                          | US-2005/0059013                          | 03-17-2005                     | The Johns Hopkins<br>University, et al.            |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |
|                       |                          | US-                                      |                                |  |   |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document                                       | Pages, Columns, Lines,<br>Where Relevant Passages or<br>Relevant Figures Appear | T <sup>6</sup> |
|-----------------------|--------------------------|---|--------------------------------|--|---|----------------|
|                       |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                       |                          | WO 2003/057014  | 07-17-2003                     | John Hopkins<br>University   |   |                |
|                       |                          | WO 2004/030511  | 04-15-2004                     | Eastern Virginia<br>Medical School, et al.   |   |                |
|                       |                          | EP 1512970  | 03-09-2005                     | Nederlandse<br>Organisatie voor<br>Toegepast-<br>Natuurwetenschappelijk<br>Onderzoek TNO |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |
|                       |                          |   |                                |  |   |                |

|                       |                    |
|-----------------------|--------------------|
| Examiner<br>Signature | Date<br>Considered |
|-----------------------|--------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

|  |   |    |   |                          |                  |
|--|---|----|---|--------------------------|------------------|
| Substitute for form 1449/PTO<br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |   |    |   | <b>Complete if Known</b> |                  |
|  |   |    |   | Application Number       | 10/760,100       |
|  |   |    |   | Filing Date              | January 16, 2004 |
|  |   |    |   | First Named Inventor     | Jonathan Heller  |
|  |   |    |   | Art Unit                 | 1631             |
|  |   |    |   | Examiner Name            | Eric S. Dejong   |
| Sheet  | 2 | of | 2 | Attorney Docket Number   | 29191-707.501    |

| NON PATENT LITERATURE DOCUMENTS            |                       |   |                |
|--|-----------------------|---|----------------|
| Examiner Initials*                         | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|  |                       | CHAMBERS, et al., "Proteomics: A New Approach to the Study of Disease". Journal of Pathology 2000; 192:280-288  |                |
|  |                       | TATAY, Jacob W., "Multiple approaches to data-mining of proteomic data based on statistical and pattern classification methods". Proteomics (2003) 3:1704-1709.   |                |
|  |                       | WANG, Michael Z., et al., "Analysis of human serum proteins by liquid phase isoelectric focusing and matrix-assisted laser desorption/ionization-mass spectrometry". Proteomics (2003), 3:1661-1666.  |                |
|  |                       | WU, Baolin, et al., "Comparison of statistical methods for classification of ovarian cancer using mass spectrometry data". Bioinformatics (2003) 19(13):1636-1643.  |                |
| CO-PENDING/PUBLISHED/ISSUED PATENT MATTERS |                       |   |                |
|  |                       | ANDEL, Frank III, et al., U.S. Patent Application No. 10/845,773 entitled "Prostate Diagnostic Patterns," filed 05-14-2004 (WSGR Reference No. 29191-719.201)   |                |
|  |                       | US-2004/0236603 published on 11-25-2004, first named inventor: Heller (WSGR Reference No. 29191-707.201)  |                |
|  |                       |   |                |
|  |                       |   |                |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.